

AUG 15 1996



## 510(k) Summary

K962508

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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**1) Submitter name, address, contact** Boehringer Mannheim Corporation  
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**2) Device name** Proprietary name: Elecsys T3  
  
Common name: Total triiodothyronine test system

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**3) Predicate device** We claim substantial equivalence to the Enzymun-Test® T3.

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**4) Device Description** The Elecsys® T3 employs a competitive test principle with polyclonal antibodies directed against T3 and with streptavidin microparticles and electrochemiluminescence detection.

Total duration of assay: 18 minutes.

- 1st Incubation: Sample (30 µl) and specific anti-T3 antibodies labeled with a ruthenium complex together with ANS to release T3 from serum.
  - 2nd Incubation: After the addition of streptavidin-coated microparticles and biotinylated T3, the still-free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex is bound to the solid phase via interaction of biotin and streptavidin.
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## 510(k) Summary, Continued

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**4) Device  
Description  
(cont.)**

- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
  - Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.
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**5) Intended use** For the *in vitro* quantitative determination of total triiodothyronine (T3) in human serum and plasma.

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**5) Indications  
for use**

Triiodothyronine (T3) is the hormone principally responsible for the development of the effects of the thyroid hormones on the various target organs.

T3 (3,5,3' Triiodothyronine) is mainly formed extra-thyroidally, particularly in the liver, by enzymatic 5'-deiodination of T4. Accordingly, the T3 concentration in serum is more a reflection of the functional state of the peripheral tissue than the secretory performance of the thyroid gland.

A reduction in the conversion of T4 to T3 results in a fall in the T3 concentration. It occurs under the influence of medications such as propranolol, glucocorticoids or amiodarone and in severe non-thyroidal general diseases - "non-thyroidal illness" (NTI) - and is referred to as the "low T3 syndrome." Like T4, over 99% of T3 is bound to transport proteins, but its affinity to them is around 10-fold lower.<sup>1-3,7</sup>

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### 5) Indications for use

The determination of T3 is utilized in the diagnosis of T3-hyperthyroidism, the detection of early stages of hyperthyroidism and for indicating a diagnosis of thyrotoxicosis factitia.<sup>4-6</sup>

#### References

- 1 Wheeler MH, Lazarus JH. Diseases of the Thyroid. Chapman and Hall Medical. London Glasgow Weinheim New York Tokyo Melbourne Madras 1994;107-115.
- 2 Pfannenstiel P, Saller B. Schilddr senkrankheiten Diagnose und Therapie. Berliner Medizinische Verlagsanstalt GmbH 1995; 2:30-32,60-62.
- 3 Fisher DA. Physiological variations in thyroid hormones physiological and pathophysiological considerations. Clinical Chemistry 1996;42:135-139.
- 4 Klee GG. Clinical usage recommendations and analytic performance goals for total and free triiodothyronine measurements. Clinical Chemistry 1996;42:155-159.
- 5 Surks MI, Chopra IJ, Mariash CN, Nicoloff JT, Solomon DH. American Thyroid Association guidelines for use of laboratory tests in thyroid disorders. JAMA 1990;63:1529-1532.
- 6 Becker DV, Bigos ST, Gaitan E, Morris JC, Rallison ML, Spencer CA, et al. Optimal use of blood tests for assessment of thyroid function (letter). JAMA 1993. 269:273.
- 7 Wild D. The Immunoassay Handbook. Stockton Press 1994; 338.

### 6) Comparison to predicate device

The Boehringer Mannheim Elecsys T3 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test® T3.

#### Similarities:

- Intended use: immunoassay for the *in vitro* quantitative determination of Total Triiodothyronine (T3)
- Competitive test principle
- Sample type: serum and plasma
- Antibody: sheep anti-T3 polyclonal
- Capture principle: streptavidin / biotin

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### 6) Comparison to predicate device (cont.) Differences:

Feature	Elecsys T3	Enzymun-Test T3
Reaction test principle	streptavidin microparticles and electrochemiluminescence technology	streptavidin-coated tubes and enzyme immunoassay technology
Sample volume	30 µl	100 µl
Instrument required	Elecsys 2010	ES 300
Calibration	a two point calibration renewal is recommended every 7 days or 1 month if the same reagent lot is used and the reagent pack is consumed within 7 days	a full calibration curve run is recommended every 2 weeks

### Performance Characteristics:

Feature	Elecsys T3	Enzymun-Test® T3
Precision:	NCCLS (modified) (EP5-T2):	Modified NCCLS "Midi" (EP3-T)
Sample N	PC U1 PC U2 HS1 HS2 HS3	1 2 3
Mean (nmol/l)	60 60 60 60 60	118 120 117
wi/in run % CV	2.12 6.31 1.22 2.87 5.09	0.95 2.56 4.26
total run % CV	4.1 3.5 3.6 4.2 5.3	2.9 1.6 1.7
	4.8 4.1 5.4 4.7 5.4	4.7 2.2 2.8
Sensitivity	Lower Detection Limit: 0.3 nmol/l 0.19 ng/ml	Lower Detection Limit: 0.46 nmol/l 0.3 ng/ml
Assay range (LDL to high std.)	0.3 - 10.00 nmol/l 0.19 - 6.51 ng/ml	0.46 - 9.22 nmol/l 0.3 - 6.0 ng/ml

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### F. Substantial Performance Characteristics: equivalence, (cont.)

Method Comparison	vs. Enzymun-Test T3 (Cat. # 1360868) Least Squares: N = 300 $y = -0.35 + 1.18x$ $r = 0.957$  Passing/Bablok N = 300 $y = -0.56 + 1.26x$ $r = 0.957$	vs. Enzymun-Test T3 (Cat. # 1135287) Least Squares: N = 55 $y = 1.13x + 0.02$ $r = 0.994$
Interfering substance: Hemoglobin Lipemia Bilirubin Biotin	No interference up to:  1 g/dl 1500 mg/dl 25 mg/dl 20 ng/ml	No interference up to:  1 g/dl 1250 mg/dl 65 mg/dl 50 ng/ml
Specificity D-T3 L-T4 D-T4 L-rT3 L-T2 3,3',5-tri-iodothyroacetic acid 3,3',5,5'-tetra-iodothyroacetic acid	% cross reaction 98.9 0.115 0.115 0.007 0.998 106.4 0.007	% cross reaction 100 0.16 0.07 0.04 1.0 7.5 0.01